REMARKS

The Examiner has rejected claims 1-5 as anticipated by Mizumoto et al., U.S. Patent No. 5,576,014. The Examiner has alleged that Mizumoto discloses an intraorally rapidly disintegrating tablet which is alleged to have the features of the claimed invention. It is believed that new independent claims 6 and 7 clearly point out and define applicant's invention in a manner that will assist the Examiner's understanding that applicant's invention is different from the Mizumoto disclosure. New claim 6 specifies an intraorally rapidly disintegrating tablet which comprises an active ingredient mixed with at least one sugar to form a core. The core is coated with a pharmaceutically acceptable disintegrating agent which substantially completely covers the core to form a granule. New claim 7 specifies an intraorally rapidly disintegrating tablet which comprises a water soluble active ingredient which constitutes a core and a coating of a pharmaceutically acceptable disintegrating agent which substantially completely covers the core to form a granule. As the Examiner recognized on page 4 of the Official Action, Mizumoto describes that an active agent may be mixed with a saccharide and other additives and that this mixture may then be coated with an aqueous solution of high moldability saccharide. Mizumoto then goes on to suggest that this aqueous solution of highly moldable saccharide can be used to coat the core and that this highly moldable saccharide aqueous solution can also contain a disintegrant. The claims before the Examiner clearly distinguish applicant's invention from Mizumoto.

According to applicant's invention as claimed, the disintegrating agent is a coating which substantially completely covers the core. While the phrase "substantially completely covers the core" is not per se used in the Specification it is clear that is what applicants have described as their invention. For example, on page 11, first full paragraph, lines 7-10, applicants state "The

phrase 'the core is coated with the pharmaceutically disintegrating agent' refers to a state in which almost all the surface of the core is sealed with the pharmaceutical disintegrating agent". This together with the other references to "coated" on page 3, second paragraph, third paragraph and fourth paragraph clearly describe the coating as substantially covering the entire core. Since it is generally the case that 100% effectiveness is not always achieved in processes, "substantially completely" is a clear and definite description of applicants' invention. Additionally the working of examples confirm this meaning. In new claim 6, the core is defined as an active ingredient mixed with at least one sugar. In new claim 7, the core is defined as a water soluble active ingredient. The purpose of a disintegrating agent is to facilitate rapid disintegration of the tablet. It achieves this by loosening adhesion between the granules constituting the tablet by absorbing water, thereby causing swelling.

According to Mizumoto at column 7 beginning at about line 19, the active ingredient is mixed with a low moldability saccharide. Alternatively, the active ingredient is mixed with granules obtained by granulating a low moldability saccharide with a high moldability saccharide. A further alternative is granulating a low moldability saccharide with both an active agent and a high moldability saccharide in any order. A further alternative is coating a low moldability saccharide with a high moldability saccharide and then with an active ingredient providing a second layer and granulating the resulting product with a high moldability saccharide. Lastly, Mizumoto describes a step of coating a low moldability saccharide with an active ingredient and granulating the coated product with a high moldability saccharide. All of these products clearly and succinctly differ from applicant's product which comprises a core substantially completely covered with a disintegrating agent. It is the fact that the core is

substantially completely covered with disintegrating agent which provides the rapid disintegration of the tablet according to applicant's invention.

When Mizumoto describes in column 13 lines 58-65 mixing an active ingredient with a low moldability saccharide and then preparing a coating solution by dissolving the active ingredient with a high moldability saccharide in water, there is no suggestion of substantially completely covering a core in a non-aqueous state with a disintegrant. It is moreover believed that if Mizumoto added a disintegrant to the coating solution, it would not perform the function performed by the disintegrating agent of the present invention. It is the disintegrating agent itself which substantially completely covers the core and thereby provides rapid disintegration of the tablet. Thus, one skilled in the art would not add a disintegrating agent to the coating solution of Mizumoto because it would defeat the purpose of using a disintegrating agent. The disintegrating agent would absorb water from the coating solution and thus cease to function as a disintegrating agent. Therefore, there is no basis for suggesting that one of ordinary skill in the art would read Mizumoto as suggesting that a disintegrating agent should instead be used to substantially completely coat the core as applicants have claimed. It is believed, therefore, that Mizumoto clearly teaches away from the invention as now clearly and succinctly defined by the claims before the Examiner, particularly new independent claims 6 and 7 and the claims which depend therefrom.

It is clear therefore that applicant's claims 6, 2-5 and 7-10 distinguish his invention from that of the cited reference and allowance on reconsideration is believed to be in order and is respectfully requested.

Upon allowance it is assumed that the PTO will follow the usual practice of renumbering certain claims so that claim 6 will be renumbered as claim 1, claims 2-5 will have the

dependency changed to claim 1 and claims 7-10 will be renumbered as claims 6-9 and the dependency of claims 7-9 will be changed to claim 6.

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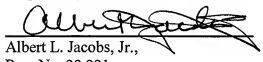
Respectfully submitted,



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